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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,970	05/03/2006	Yukiko Sugihara	06303/HG	7540

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EXAMINER	
LAU, JONATHAN S	

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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,970	SUGIHARA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010 and 15 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-27* is/are pending in the application.

4a) Of the above claim(s) *9-18 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8 and 19-22* is/are rejected.

7)☒ Claim(s) *23-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 Jan 2010 has been entered.

Applicant's Supplemental Amendment and Remarks, filed on 15 Jun 2010, in which claim 21 is recited will be entered as the supplemental reply is clearly limited to adoption of the examiner's request of 15 Jun 2010.

This Office Action is responsive to Applicant's Amendment and Remarks, filed on 14 Jan 2010, in which claim 1 is amended to change the scope and breadth of the claims, claims 6 and 19 are amended to change the dependency of the claim, and claim 5 is canceled; and Applicant's Supplemental Amendment and Remarks, filed on 15 Jun 2010, in which claim 21 is recited.

This application is the national stage entry of PCT/JP04/17031, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-380194, filed 10 Nov

2003; currently an English language translation of this foreign priority document has not been made of record.

Claims 1-3 and 6-27 are pending in the current application. Claims 9-18 and 27, drawn to non-elected inventions, are withdrawn. Claims 19-26 are rejoined herein. Claims 1-3, 6-8 and 19-26 are examined on the merits herein.

Election/Restrictions

Upon further review of the invention as claimed, the restriction requirement between groups I and III, detailed in the Office Action mailed 13 Nov 2007 is **withdrawn**.

Claims 19-26 are rejoined and examined on the merits herein.

Rejections Withdrawn

Applicant's Amendment, filed 14 Jan 2010, with respect to claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006) has been fully considered and is persuasive, as claim 5 is canceled and amended claim 1 recites the concentration of said polysaccharide is 0.0001 to 0.01 wt%.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 14 Jan 2010, with respect to claims 1-3 provisionally rejected on the ground of nonstatutory double patenting over amended claims 6-11 and 13-16 of copending Application No. 10/486122 has been fully considered and is persuasive, as amended claim 1 recites the concentration of said polysaccharide is 0.0001 to 0.01 wt% and the status of copending Application No. 10/486122 is abandoned.

This provisional rejection has been **withdrawn**.

Applicant's Amendment, filed 14 Jan 2010, with respect to claims 1-3 and 5-8 provisionally rejected on the ground of nonstatutory double patenting over amended claims 1-3 and 5-13 of copending Application No. 11/810524 has been fully considered and is persuasive, as claim 5 is canceled and amended claim 1 recites the concentration of said polysaccharide is 0.0001 to 0.01 wt%.

This provisional rejection has been **withdrawn**.

Claim Objections

Claims 23-26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition used for treating dry eye by stabilizing a tear film of an eyeball surface, does not reasonably provide enablement for a composition used for preventing dry eye by stabilizing a tear film of an eyeball surface. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: An agar-containing ophthalmic composition used for treating or preventing dry eye by stabilizing a tear film of an eyeball surface.

The state of the prior art: The ordinary definition of the term prevent encompasses the definition "to render (an intended, possible, or likely action or event) impractical or impossible by anticipatory action" (definition 9a. of prevent, Oxford English Dictionary, cited in PTO-892).

One of ordinary skill in the art would understand it is possible that any ophthalmic composition stabilizing a tear film can dry by evaporation or dry after removal such as by mechanical action of blinking, therefore dry eye cannot be rendered impossible by use of a ophthalmic composition to stabilize a tear film of an eyeball surface.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The sheer number of possible patients treated and time period for treatment means that one skilled in the art cannot predict the usefulness for all possible agar-containing ophthalmic compositions used for preventing dry eye by stabilizing a tear film of an eyeball surface. Therefore the claimed invention encompassing the scope of compositions used to render dry eye impossible is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Any possible patient population or treatment duration can be employed in the intended use of preventing dry eye by stabilizing a tear film of an eyeball surface.

The amount of direction or guidance presented: The specification speaks generally about the frequency of administration and the effect over a prolonged period of time at page 19. It is suggested that the tear film stabilizing effect is attributable to uniform dispersion on the mucous surface (page 26-27). However, guidance is not

given for intended use of rendering dry eye impossible by stabilizing a tear film of an eyeball surface.

The presence or absence of working examples: The only working examples provided are for stabilizing the tear film of an eyeball surface by measuring spherical irregularity after 30 minutes at pages 25-26.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as agar-containing ophthalmic compositions used to render dry eye impossible. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible agar-containing ophthalmic compositions beyond those known in the art, (such as agar-containing ophthalmic composition used for treating dry eye by stabilizing a tear film of an eyeball surface) one skilled in the art would undertake a novel and extensive research program into preventing dry eye. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of patient populations or treatment durations for the intended use of preventing dry eye, it would constitute an undue and unpredictable experimental burden.

> *Genentech*, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the

claimed invention for all possible agar-containing ophthalmic compositions used for preventing dry eye by stabilizing a tear film of an eyeball surface.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended Claims 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006; English language equivalent US Patent Application Publication 2004/0266725 of record).

Inohara et al. discloses a composition containing a polysaccharide in water (abstract). Inohara et al. discloses a composition containing the 0.1 wt % of the polysaccharide agar in water (page 2, paragraph 26), meeting limitations of instant claim 20. Inohara et al. discloses said composition useful for application to an ocular mucous membrane in the form of a topically applied eyedrop with excellent characteristics (page 6, paragraph 62), implicitly meeting all structural limitations of the intended use of "stabilizing a tear film on an eyeball surface" of instant claim 20 or treating dry eye by stabilizing a tear film on an eyeball surface of instant claim 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-8 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inohara et al. (WIPO Publication WO 2003/013612, published 20 Feb 2003, provided by Applicant in IDS mailed 03 May 2006; English language equivalent US Patent Application Publication 2004/0266725 of record) in view of Bourlais et al. (Progress in Retinal and Eye Research, 1998, 17(1), p33-58, cited in PTO-892) and Van Santivliet et al. (European Journal of Pharmaceutical Sciences, 1999, 7, p339-345, cited in PTO-892).

Inohara et al. discloses as above. Inohara et al. teaches the viscosity of said eyedrop may preferably be adjusted to 150 mPa*s or less (page 6, paragraph 66).

Inohara et al. does not specifically teach the concentration of said polysaccharide is 0.0001 to 0.01 wt% and the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour (instant claim 1). Inohara et al. does not specifically disclose the composition being operable to be uniformly dispersed on a mucous membrane when topically administered to a mammal (instant claim 6) and wherein the mucous membrane is an ocular mucous membrane (instant claim 7). Inohara et al. does not specifically teach the composition as a contact lens-wearing solution or a contact lens preservative solution (instant claim 19). Inohara et al. does not specifically teach the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000 xg for one hour and the composition being characterized by uniformly dispersing on an ocular surface when administered in the eye (instant claim 22).

Bourlais et al. teaches the level of skill in the art with regard to eyedrops as conventional dosage forms for ophthalmic formulations (page 34, abstract). Bourlais et al. teaches eyedrops made of polymeric gels are known in the art (page 36, section 2. POLYMERIC GELS at right column). Bourlais et al. teaches highly viscous solutions of bioadhesive hydrogels are often associated with discomfort and result in blurred vision (page 40, right column, paragraph 2 and page 41, left column, paragraph 1).

Van Santivliet et al. teaches the level of skill in the art with regard to eyedrops as conventional dosage forms for ophthalmic formulations (page 339, abstract). Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s (page 339, right column, paragraph 1). Van Santivliet et al. teaches that it is

expected to one of ordinary skill in the art that for a given solution, increasing concentration of the viscolyser will increase the viscosity of the solution (page 343, table 3 at bottom of page).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Inohara et al. in view of Bourlais et al. and Van Santivliet et al. All of Inohara et al., Bourlais et al. and Van Santivliet et al. are drawn to eyedrops as conventional dosage forms for ophthalmic formulations. One of ordinary skill in the art would have been motivated to combine Inohara et al. in view of Bourlais et al. and Van Santivliet et al. in order to optimize the concentration of said polysaccharide to be 0.0001 to 0.01 wt% because Inohara et al. teaches the viscosity of said eyedrop may preferably be adjusted to 150 mPa*s or less, Bourlais et al. teaches highly viscous solutions of bioadhesive hydrogels are often associated undesirable side effects, and Van Santivliet et al. teaches the ideal viscosity of an ophthalmic solution is estimated at 15-30 mPa*s. One of ordinary skill in the art would have had a reasonable expectation of success in combine Inohara et al. in view of Bourlais et al. and Van Santivliet et al. because Van Santivliet et al. teaches that it is expected to one of ordinary skill in the art that for a given solution decreasing concentration of the viscolyser will decrease the viscosity of the solution. It would have been obvious to one of ordinary skill in the art that the amount of precipitated polysaccharide after performing centrifugal separation at 25 °C with 40,000x g for one hour would have been less than 65 wt%, 55 wt% or 30 wt% because the invention of Inohara et al. teaches agar obtained in the state of a liquid composition not in the state of a gel (page 2, paragraph 26) having a low viscosity

during storage (page 3, paragraph 36) and giving a liquid composition without gelling (page 4, paragraph 48 and page 7, paragraph 73). It would have been obvious to one of ordinary skill in the art that the composition taught by Inohara et al. in view of Bourlais et al. and Van Santivliet et al. teaches all structural limitations of the composition capable of performing the intended use of being "operable to be uniformly dispersed on a mucous membrane when topically administered to a mammal" and "wherein the mucous membrane is an ocular mucous membrane" of instant claims 6 and 7.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amended Claims 20 and 21 are provisionally rejected on the ground of nonstatutory double patenting over amended claims 1, 3, 5, 7 and 9-11 of copending

Application No. 11/810524. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Amended Claims 1, 3, 5, 7 and 9-11 of copending Application No. 11/810524 are drawn to an eyedrop composition comprising a polysaccharide agar and water, implicitly meeting all structural limitations of the intended use of "stabilizing a tear film on an eyeball surface" of instant claim 20.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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